

# **EXHIBIT 8**

# **AmerisourceBerg en**

**2009 National Healthcare  
Conference**

**State & Federal Regulatory  
Issues**

**That Impact The Pharmaceutical  
Industry**

**August 8, 2009**

# Chris Zimmerman, CPP, CFE

Vice President, Corporate Security &  
Regulatory Affairs, AmerisourceBergen  
Corporation

25 years of healthcare industry  
experience, the last 20 years with  
AmerisourceBergen Corporation in  
Regulatory Affairs and Corporate Security  
Active member of HDMA's Government &  
Public Policy Council, Regulatory and  
Government Affairs Committee, Chairman  
of Anti-Counterfeit Task Force

- Active member and Chairman of the  
American Society for Industrial Security's  
Pharmaceutical Security Council's  
Membership Committee
- Board Certified Protection Professional  
and Fraud Examiner



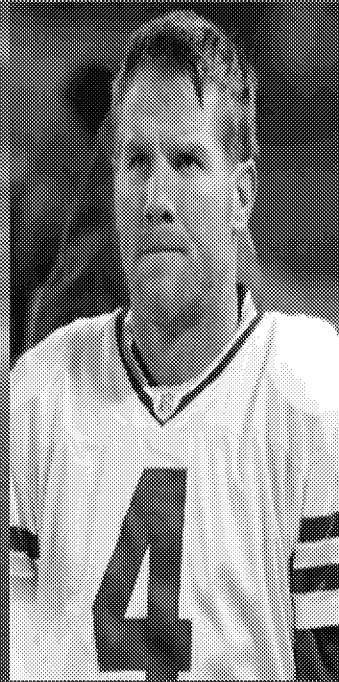
# Background

- Audience
  - Geography
  - History
- Perspective
- Process
- Handouts



# Objectives

- Increase Awareness to the Dramatic Increase in Prescription Drug Abuse in the U.S.
- Understand ABC's Diversion Control Program
- Offer "Best Practices" Solutions for DEA Compliance
- Discuss Current Legislative & Regulatory Initiatives:
  - **Ryan Haight Online Pharmacy Consumer Protection Act**
  - **Prescription Drug Disposal**
  - **Pedigree**
  - **Methamphetamine Production Prevention Act**
  - **FDA Risk Evaluation and Mitigation Strategies (REMS)**
  - **Marketing of Unapproved Narcotics**





# Prescription Drug Abuse in the U.S.

- In 2007, an estimated 2.7 Million persons aged 12 or older used an illicit drug for the first time. Three fifths were younger than age 18 when they first used.
- Non-medical use of prescription drugs ranks ~~second only to marijuana~~ as the most prevalent category of drug abuse.
- In both 2006 and 2007, an estimated 5.2 Million persons aged 12 or older were current non-medical users of prescriptions pain relievers.\*

\*

2007 NSDUH – SAMHSA



# Prescription Drug Abuse in the U.S.

- 2008 Annual Survey by the University of Michigan
  - 386 public and private schools
  - 46,348 students
- Prescription/over-the-counter drugs account for 7 out of 11 of the most frequently abused drugs
- Nearly 1 in 10 High School Seniors have abused Vicodin
- Nearly 1 in 20 High School Seniors have abused Oxycontin

# Prescription Drug Abuse in the U.S.

- "In 2008, 3,000 people died in Florida from prescription drug overdoses – **three times the deaths** attributable to illegal drugs. The problem is multifaceted: teens raiding medicine cabinets; those in chronic pain taking too much of their prescription; addicts who doctor shop to secure a new prescription for their next high."
- "In the second half of 2008, the top 50 doctors dispensing oxycodone nationwide were all in Florida, including 33 in Broward County, according to DEA."

\*St. Petersburg Times – June 3, 2009



# Hydrocodone Growth vs Population Growth 1990 – 2007\*

- Between 1990 and 2007
  - 21% growth in population
- Between 1990 and 2007
  - 280% increase in distribution of hydrocodone
- 99%** of all hydrocodone manufactured in the World is consumed in the United States.

Enforcement Administration

\*Drug



# Current Schemes – Pain Clinics

- East Coast Hub: Florida Pain Clinics
  - Heavy concentrations in Miami-Dade, Broward and West Palm Beach counties
  - MD visit and dispense from same location
  - Primarily cash; \$200 for initial visit, \$150 for follow-up visit
  - \$825 - \$950 for cocktail (Soma, Valium & Oxycodone)
  - \$1.50 - \$2.00 per pill from non-affiliated pharmacy
  - \$3.00 - \$4.00 per pill from pain clinic's in-house pharmacy
  - Average 120 – 180 pills per prescription
  - Out of state patients
    - Distribution to identified states of Maryland, Virginia, Kentucky, Tennessee and Ohio for \$30-\$40 per pill
    - DTOs transport patients to clinics every two weeks to meet with as many doctors as possible during 2-3 day timeframe

\*Drug

Enforcement Administration

# Pain Clinics

- Houston Hub
  - Distribution networks to neighboring states: LA, AR & MS
  - Prescriptions being filled in Texas, then carried to state of origin
  - Medical visits range from \$85 - \$100
  - Most commonly written is hydrocodone
  - Average \$55 to fill Rx for 120 pills
  - Closed system (Rx is faxed to partnering pharmacy)
  - Partnering pharmacy sells narcotics at reduced rate to avoid extra scrutiny
  - Owners of pain clinics are usually non-DEA registrants
  - Pain clinics hire a medical director who is a DEA registrant
    - Signs blank prescription pads
    - Shows up at clinic once every few days

Enforcement Administration

\*Drug



# Pain Clinics

- West Coast Hub: Los Angeles
  - Distribution networks north along the west coast to Seattle
  - To Las Vegas, Houston, Louisiana, Memphis, and Atlanta; U-Hauls and express mail services
  - Similar to Florida pain clinics; however clinics issue prescriptions which are filled at “approved” pharmacies (partnered with physicians)
  - Patients travel from all over California and out of state to visit “Pill Mill” clinics; regularly transported in by bus/van by DTOs.

\*Drug

Enforcement Administration



# Doctor Shopping

- › Individual Patients
  - Target Physicians
    - Obtain prescriptions from multiple physicians
    - Physicians willing to prescribe controlled substances over extended period of time with little or no follow-up
  - Target Pharmacies
    - Utilize multiple pharmacies to fill orders
    - Pharmacies known to dispense controlled substances without asking questions

\*Drug

Enforcement Administration

# Doctor Shopping

- Trafficking Organizations
  - Recruit individuals to obtain narcotics
    - Targets often have legitimate medical conditions (favorite targets: seniors, nursing homes, homeless shelters)
    - With cooperating physician or staff, patients never see physician
      - False identification, obtained from consenting individuals, used to “create” medicals records and obtain scripts
    - Pay patients for their narcotics and services
  - Target physicians
    - Those known to prescribe with little or no follow-up
    - Sympathetic to patients’ medical situation
    - Commonly long distance from patients’ residence
  - Well organized
    - Often provide transportation of patients to/from physicians and pharmacies

\*Drug

Enforcement Administration



# Prescription Fraud

- Fake prescriptions
  - Often highly organized
  - Use real physician name and DEA number
    - Contact information false or “fake office”
    - Organizations set up actual offices with contact information and staff (change locations often to avoid detection)
  - Prescription printing services utilized
- Stolen prescriptions
  - Forged
  - “Smurfed” to large number of different pharmacies

\*Drug

Enforcement Administration



# DEA Regulatory Update

- Recent DEA Enforcement Actions
  - Cardinal settles w/DEA (**\$34M**)
  - McKesson settles w/DEA (**\$13.7M**)
  - Rite Aid Corporation settles w/DEA (**\$5M**)
  - Masters Pharmaceutical settles w/DEA (**\$500,000**)

***Masters Pharmaceutical, Inc.  
Sold 4.2 Million Doses of  
Hydrocodone, Phentermine and  
Alprazolam without Reporting  
Sales to DEA***

# Changes In DEA

- Diversion Investigator vs. Drug Enforcement Agents
- Increase in field investigations
- Distributors are viewed as a “choke point” for diversion control by DEA
  - Over 66,000 DEA Registered Pharmacies
  - Over 1 Million DEA Registered Practitioners
  - Less than 900 DEA Registered Distributors (“big three” = 90%)
- Increased focus on sales associates and front line distributor employees (customer service, drivers, etc.)



# Regulatory Responsibility

Title 21 of the Code of Federal  
Regulations:

**1301.71(a)** – “All  
applicants and registrants  
shall provide effective controls  
and procedures to guard  
against theft and diversion of  
controlled substances.”

# ABC's Diversion Control Program

- "Know Your Customer" Due Diligence
- Order Monitoring Program (OMP)
- Investigations
- Education and Training



# ABC's Diversion Control Program

On a monthly basis ABC conducts approximately:

- 4,000 – Suspicious Order Reviews
- 100 – NCDD Investigations
- 20 – Suspicious Order Investigations

# Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders & Preventing Diversion of Controlled Substances

## HDMA Guidelines – October 2008

- Know your customer Due Diligence
- Monitoring for Suspicious Orders
- Suspend/Stop an Order of Interest Shipment
- Investigation of Orders of Interest
- File Suspicious Order Reports with DEA
- Employees, Training and SOPs.

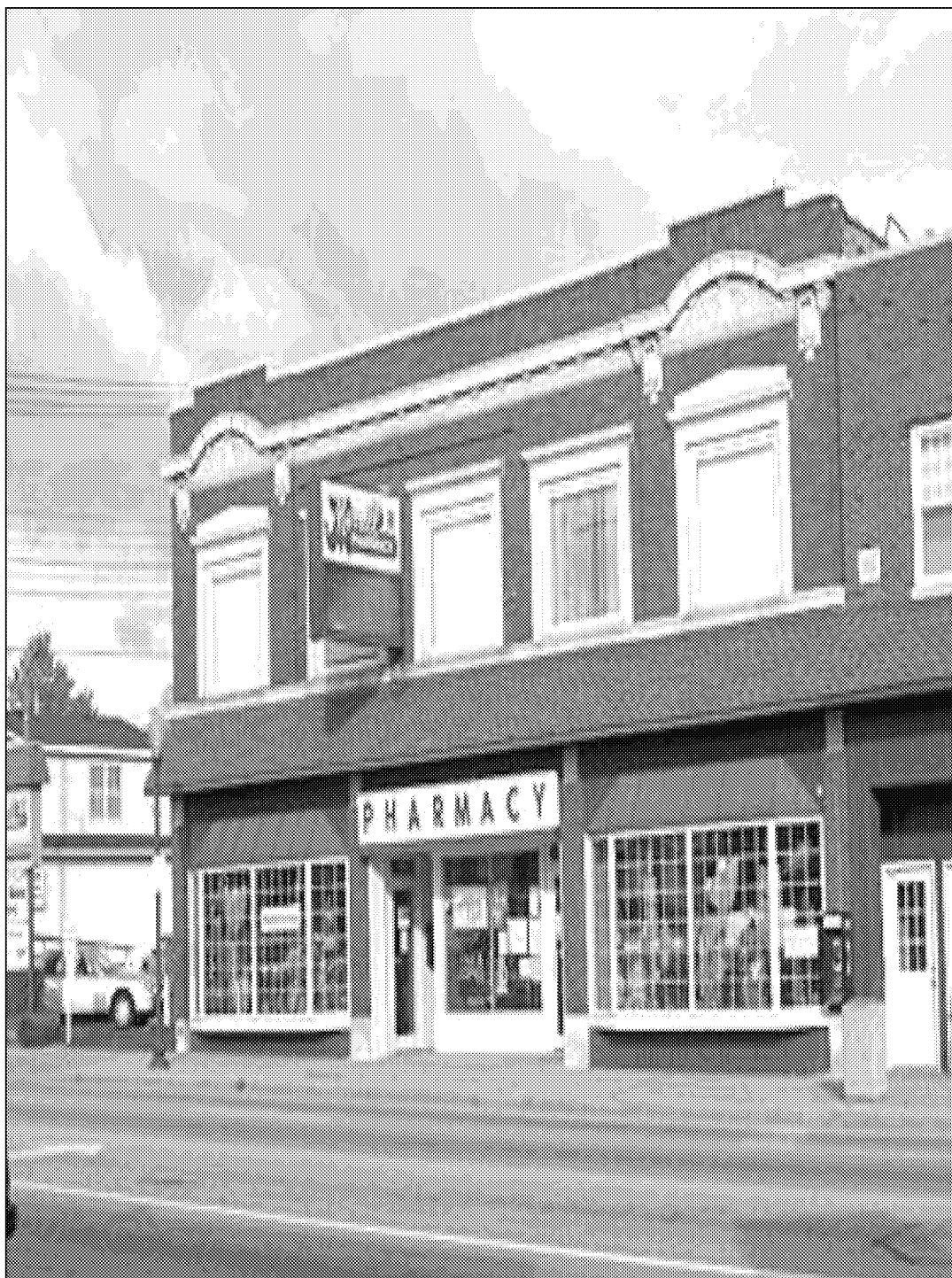
## ABC DCP – April 2007

- Know your customer Due Diligence
- Monitoring for Suspicious Orders
- Suspend/Stop and Order of Interest Shipment
- Investigation of Orders of Interest
- File Suspicious Order Reports with DEA
- Employees, Training and SOPs
- Customer education, Model P&P, CSRA visits, On-going enhancements to OMP.



# New Customer Due Diligence

- **"Know Your Customer"** Due Diligence investigations completed on all new Retail and Wholesale Accounts.
- New Account Questionnaire
- Information Verification
- Internet Search
- On-site visit includes photographs inside and out (or physical description of premises)



























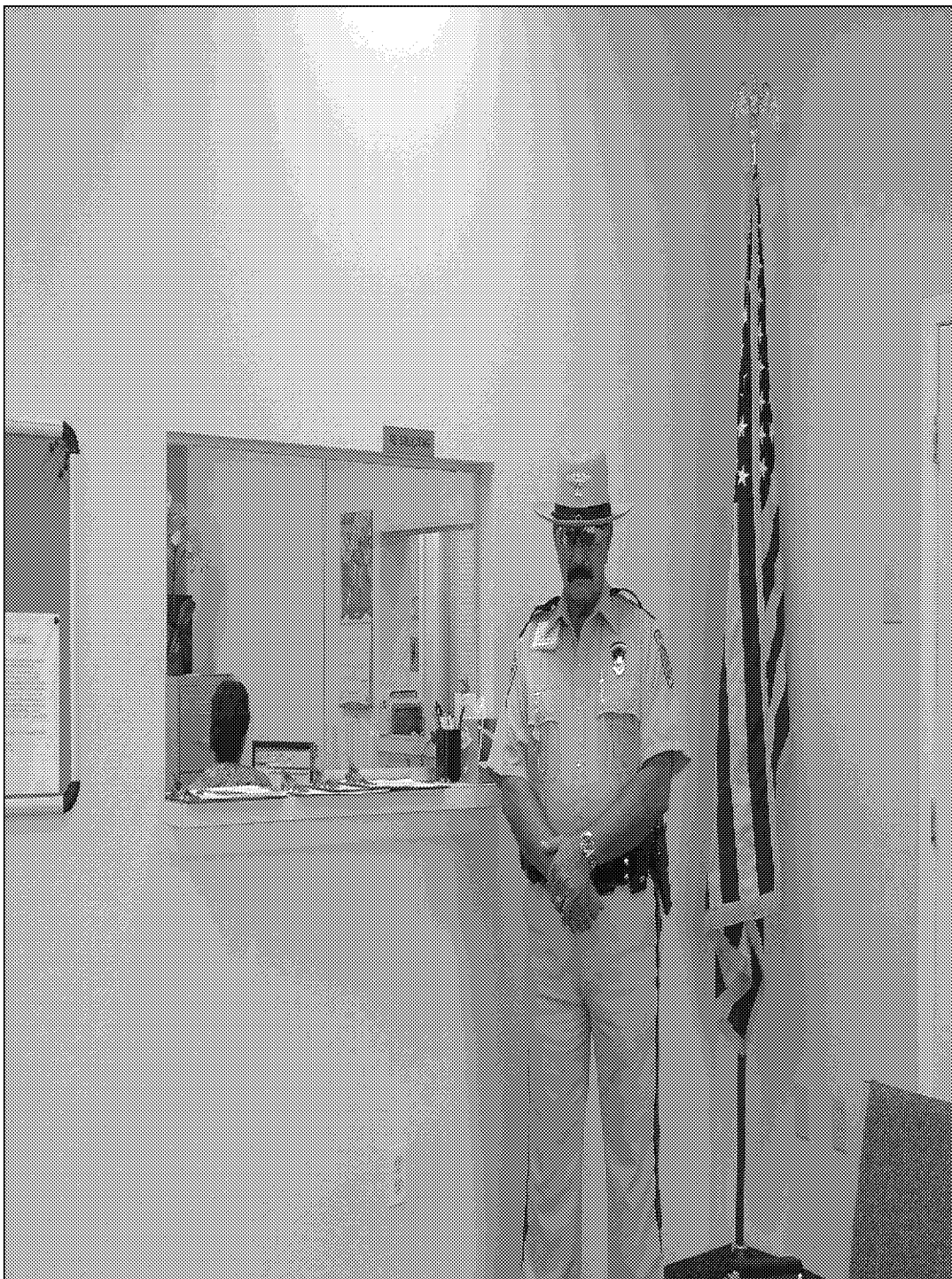
















# ABC's Diversion Control Program

- "Know Your Customer" Due Diligence
- **Order Monitoring Program (OMP)**
- **Investigations**
- **Education and Training**



# Order Monitoring Program (OMP)

- Customers classified in OMP according to DEA business activity.
- Total monthly dollar volume = customer size
- Thresholds = average of CS products purchased by like classified customers + 300%.
- Thresholds are continually evaluated based on variables such as business model, location, specialties, etc.

# Investigations

- Suspicious Order Investigations
  - Order flagged by OMP
  - Unusual size, deviates substantially from a normal pattern, unusual frequency, item type.
  - Purchase history.
  - Dollar volume/product mix.
  - Ratio of CS to Non-CS purchases.
  - Contact with customer.
  - Is there a rationale for the order?
  - Site visit.
  - Responsibility not to ship a suspicious order.



# Review of Monthly Data

- Top purchasers of high risk controls and selected non-controls.
- CS ratio report.
- Help identify potential problems.
- Analyzed in 6-month blocks.
- Trending.
- Can bring to light a problem the customer does not know exists, i.e. internal diversion.

# Tramadol & Carisoprodol (Soma)

- Federal – Non-Controlled substances.
- State – CS in AL, AZ, HI, IN, KY, NV, NM, OH, OR, WV.
- Listed as “drugs of concern” by the DEA.
- High volume purchases may be indicative of Internet sales.
- Brick-n-mortar pharmacies are solicited to fill and mail prescriptions received through internet sites for a set fee.



# Education and Training

- NADDI – National Association of Drug Diversion Investigators.
- Cluster meetings.
- On site training.
- Model policies and procedures.

## Order Monitoring Program and Diversion Control



AmerisourceBergan® is committed, along with our supply chain partners, to preventing the diversion of controlled substances. We have taken a leadership role in developing and implementing programs that help identify instances of diversion — and it is only with your help that we ensure the safety of the pharmaceutical supply chain.

### Current Regulations

One of the DEA's highest priorities nationwide is to eliminate the diversion and abuse of controlled substances. All individuals and firms who handle controlled substances must be registered with the DEA. As a DEA registered pharmacy, you are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances," Title 21, Code of Federal Regulations, parts 1300 to 1316.

Furthermore, the DEA is requiring wholesalers, including AmerisourceBergan, to take a more active role in monitoring the ordering of controlled substances. In response, we have taken the lead in developing an enhanced Order Monitoring Program.

### About our Order Monitoring Program

- The Order Monitoring Program is the cornerstone of our diversion control effort. The program helps to alert customers of significant changes in order quantities and can assist in resolving variances.
- Monthly controlled substance thresholds are established for each customer and are based on three factors:
  - DEA registrant type (hospital, retail, clinic, physician, etc.)
  - Customer size by sales volume
  - Item family (particular classes of drugs or chemicals)
- Threshold levels for controlled substances can be adjusted depending upon your business practices and/or treatment specialty.

### How AmerisourceBergan can help you

- AmerisourceBergan has developed "Pharmacy Guidelines for DEA Compliance" which are suggested Best Practices for our customers — to help you gain confidence in your compliance with DEA regulations.
- A team of dedicated investigators, analysts and support personnel will assist our customers to help prevent diversion and remain compliant with federal regulations.
- AmerisourceBergan's Corporate Security and Regulatory Affairs staff will work closely with customers to minimize impact on compliant customers' orders.

Prescription drug diversion and abuse will continue to be a serious problem with far-reaching implications for public safety and the pharmaceutical industry. AmerisourceBergan remains an industry leader in addressing those concerns — and we will continually enhance our program — for our pharmacy partners.

If you have any questions about AmerisourceBergan's Order Monitoring Program or your pharmacy's purchasing levels, contact your Account Manager.

To learn more about "Pharmacy Guidelines for DEA Compliance," contact your Account Manager or Ed Hazeewski, AmerisourceBergan Diversion Control Manager at 610-727-3580 or [ehazeewski@amerisourcebergan.com](mailto:ehazeewski@amerisourcebergan.com)





# Partnering With Our Customers

- CSRA will attend cluster meetings or other customer events to present topics of concern / interest
- CSRA, in cooperation with the ABC management staff, is developing a video library for use by our customer base
  - Robbery / Burglary Prevention
  - Shrinkage / Loss Prevention
  - Diversion Control



# Rx PATROL

[WWW.rxpatrol.org](http://WWW.rxpatrol.org)

An information clearinghouse about pharmacy robberies, burglaries and theft of controlled substances

Collects, analyzes and shares information to:

- Help protect pharmacists
- Guard against potential robberies and burglaries
- Assist law enforcement efforts to apprehend and successfully prosecute those engaged in pharmacy theft of controlled substances

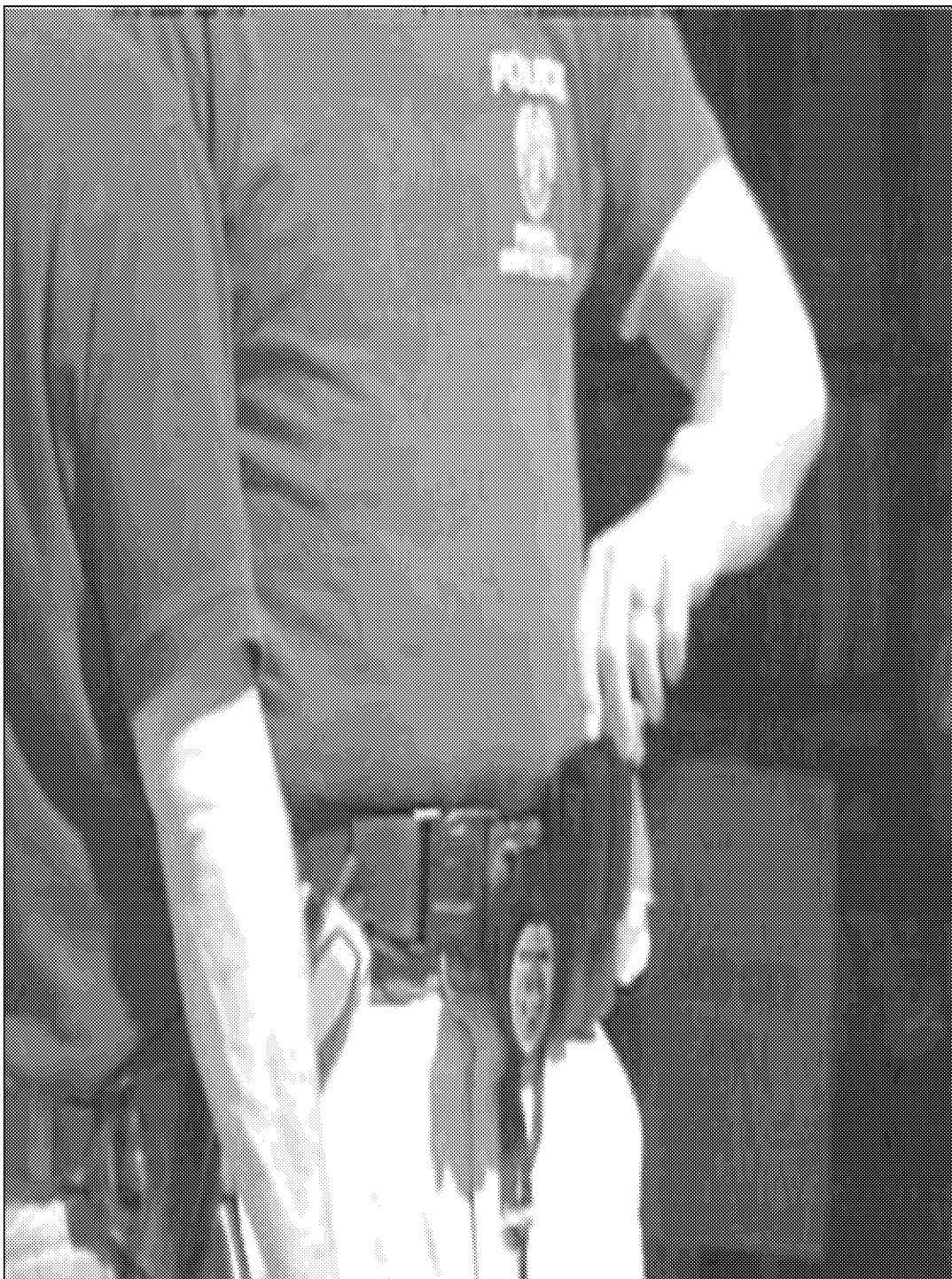
Uses state-of-the-art computer program to collate, analyze and disseminate information to the law enforcement community.

Analyzes patterns to create profiles of vulnerable pharmacies and of effective security systems for deterring burglars and robbers.

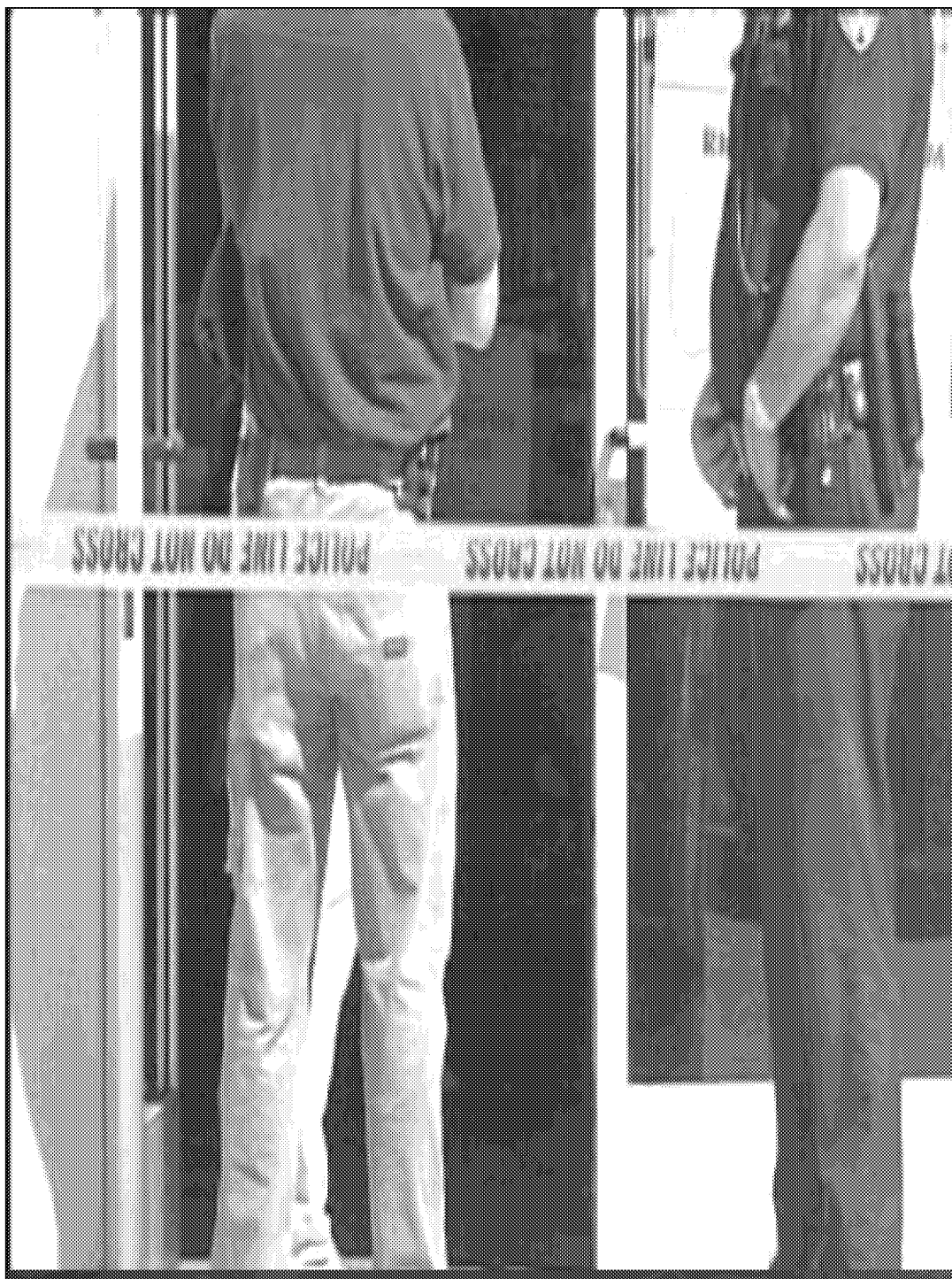
Training Videos – Pharmacy Safety, Scams, Diversion





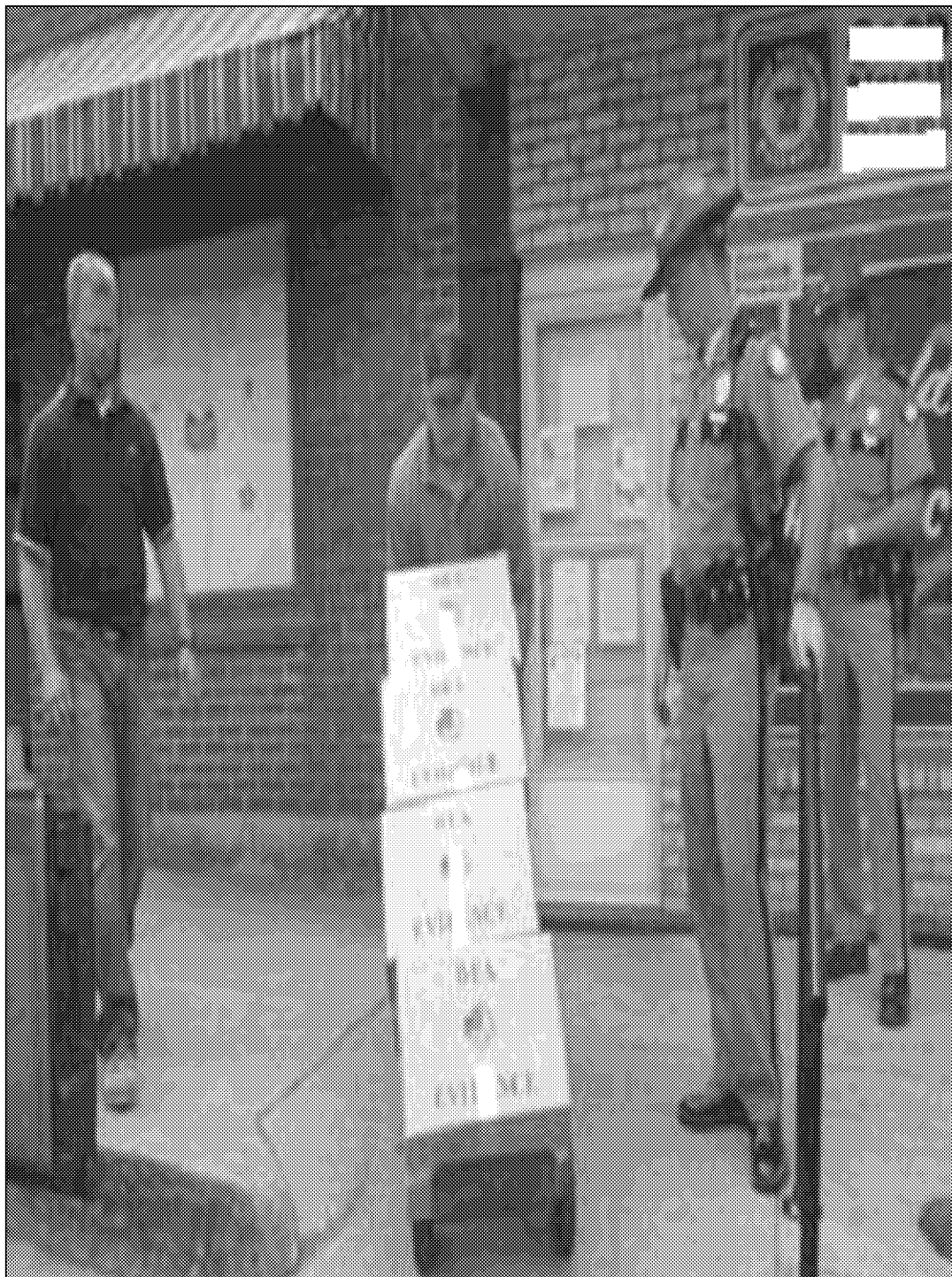


















**WHAT CAN YOU  
DO?**

# Regulatory Responsibility

Title 21 of the Code of Federal  
Regulations:

**1301.71(a)** – “All  
applicants and registrants  
shall provide effective controls  
and procedures to guard  
against theft and diversion of  
controlled substances.”



# ABC Model Policies & Procedures For Retail Pharmacies

- Based on industry best practices and the Code of Federal Regulations.
- Addresses issues concerning the ordering, receiving, security, and handling of controlled substances.
- Intended to be a model for ABC pharmacy customers to follow to develop their own P & Ps.
- A valuable tool in assisting the pharmacy to keep compliant with Federal and State law and regulations.

# Policies & Procedures

- Introduction – Logic & “Best Practices”
- Areas to Include in Policies & Procedures
  - DEA Registration
  - Recordkeeping
  - Ordering and Receipt of Controlled Substances
  - Security and Storage
  - Inventory



# Policies & Procedures

- o Policy & Procedure Areas, cont.:
  - “Disposal” of Controlled Substances
  - Diversion
  - Methamphetamine Control Act
  - Prescriptions
  - Controlled Substance Dispensing
  - Pain Clinic Patients

# Controlled Substance Prescriptions "Know Your Customer"

- Patient Name and Address
- Date Written
- Drug Name, Strength, Directions, & Quantity
- Prescribing Physician's Name, Address & DEA #
- Need All the Above **AND** Patient has a Legitimate Medical Reason for the Prescription to be Valid



# Dispensing

- Visually Inspect Prescriptions for Potential Forgery and/or Alteration
- Review Patient Profile for Appropriateness of Therapy
- Review State Prescription Monitoring Data (if available) or Make Other Attempts to Determine Multiple Prescribers/Pharmacies
- Phone Verify All New Patients and Prescriptions From Unknown Physicians

# Dispensing

- You Want How Many?
  - Validate the Appropriateness of what the Physician Writes
- Limit Who Can Pick Up Prescriptions to Only Those Authorized by the Patient
- Require Identification for Prescription Pick Up



# Pain Clinic Patient Management

- Pain Clinic's Prescribers Should be Open and Willing Participants to Answer Questions
- Pain Clinic Implemented "Pain Contracts" with Patients to Spell Out the Patient's Rights and Responsibilities Regarding Pain Therapy
- Pharmacy Maintains Copies of Those Contracts if possible
- Medication "Counts"
- Prescriptions Tamper Resistant

# Pain Clinic Patient Management

- Set a Minimum Fill Time (recommend at least 30 min)
- Establish a Procedure for “Lost” or Stolen Prescriptions & Medications that Includes Notification of the Police and Prescriber
- Establish Routine “Training Programs” for Pharmacy Staff that Focuses on Identification of Fraudulent Prescriptions & Patients
- Establish Routine Documentation Procedures for Conversations with the Pain Clinic Staff and for Situations that Arise for the Patient While on Service





# **Recent Federal and State Regulatory Activity**

# Ryan Haight Online Pharmacy Consumer Protection Act

- Legislation enacted on 10/15/2008
- Amends the CSA adding new provisions to prevent illegal distribution of controlled substances by Internet
- Expands the definition of valid prescription to include at least one "face-to-face" medical evaluation



# Ryan Haight Online Pharmacy Consumer Protection Act

- New DEA registration requirements for all Internet pharmacies
  - Modification of existing DEA pharmacy registration
  - New DEA number identifier and business activity code
- Reporting requirements
  - Number of prescriptions, dosage unit totals

# Ryan Haight Online Pharmacy Consumer Protection Act

- Disclosure requirements for Internet pharmacy's home page
  - Identify and post address and phone number of servicing pharmacies, pharmacist in charge and physicians
- Effective date of 4/13/2009
- Requires rulemaking by DEA concerning telemedicine
- **DEA has received five (5) applications as of the end of June 2009.....????**



# Prescription Drug Disposal

- FDA Drug Disposal Guidelines Published 6/2008
- Office of National Drug Control Policy reiterated those Guidelines 1/2009
- Focus is medications in the public's possession that are "no longer in use"
- Doesn't differentiate prescription meds from controlled substances disposal

# Prescription Drug Disposal

- Federal Guidelines:
  - Don't flush unless there is specific instruction to do so (on label or patient information)
  - Check for community drug take back programs or household hazardous waste collection events that include medications



# Prescription Drug Disposal

- If drug take back or collection not available
  - Remove medications from original container
  - Mix drugs with “undesirable” substance (cat litter or coffee grounds) and seal in a plastic container or sealable bag
  - Remove any personal information from the empty original containers
  - Place sealed container with medication mixture and empty drug containers in trash

# Prescription Drug Disposal

- Federal Legislative Efforts to Address Prescription Drug Disposal:
  - Clean Water Act (EPA)
  - Universal Waste Rule (EPA) – Addition of Pharmaceuticals (Pending)
  - Drug Free Water Act of 2009 (EPA) (Pending)
  - Safe Drug Disposal Act of 2009 (DEA) (Pending)
  - DEA ANPRM “Disposal of controlled substances by persons not registered with the Drug Enforcement Administration” (1/2009)



# Prescription Drug Disposal

## Other Efforts

- State Legislation (Maine, Oregon, Wash)
- Pharmacy & Hospital collection events (single day & ongoing)
- Municipal or county events (single day)
- Maine mail back program
- Reverse Distributor pilot (WI)

# Controlled Substance Disposal

- ANPRM Published in Federal Register on 1/21/2009
- Entitled "Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration"
- Seeks options for safe and responsible disposal of patient-owned controlled substances consistent with CSA



# Methamphetamine Production Prevention Act of 2008

- Enacted on 10/14/2008
- Amends the CSA adding new provisions regarding logbook requirements
- Permits mix of manual and electronic
- Allows certain info to be captured electronically, while other info is captured in a written log.

# Federal PDMA Timeline

1987:  
Prescription Drug  
Marketing  
Act

May 2000:  
Pedigree  
portion of  
final  
regulation  
stayed again  
until October  
2001

February  
2002:  
Pedigree  
portion of  
final  
regulation  
stayed again  
until April  
2003

February 2004:  
Pedigree  
portion of final  
regulation  
stayed again  
until December  
2006

December 4,  
2006: US  
District Court  
grants  
temporary  
injunction  
RxUSA

December-  
1999: Final  
regulations  
effective;  
pedigree  
portion stayed  
until October  
2001

March 2001:  
Pedigree portion  
of final  
regulation  
stayed again  
until April 2002

January 2003:  
Pedigree portion  
of final  
regulation  
stayed again  
until April 2004

December 1,  
2006: PDMA  
Implemented

July 13, 2008:  
US Court of  
Appeals affirms  
preliminary  
injunction



# State Pedigree Update

- Between 2003-2009, 28 states enacted some form of pedigree legislation
  - “Normal” or “Primary” Distribution Model in 19 states (AZ, CO, GA, ID, IL, IN, KS, MD, MS, NE, ND, OK, OR, SD, TX, VA, WI, WY)
  - Requires pedigree (back to manufacturer) outside designated distribution channel
  - Seven others adopted PDMA or similar models
  - California – “Track and Trace” Model
  - Florida – Standard or “Direct Purchase” Pedigree

# 2009 HDMA Map of State Pedigree Legislation/Regulations

As of February 27, 2009





# FDA's Risk Evaluation and Mitigation Strategies (REMS)

- Food & Drug Amendments Act of 2007 provides FDA with Authority to:
  - Require post-marketing studies and clinical trials
  - To demand safety related labeling changes
  - Demand the development and compliance with REMS

# FDA's Risk Evaluation and Mitigation Strategies (REMS)

- FDA Established Guidelines for:
  - New Drug Applications (NDA)
    - Criteria used to determine need for REMS includes:
      - **Size of population likely for treatment**
      - **Seriousness of disease**
      - **Anticipated drug benefit**
      - **Anticipated duration of therapy**
      - **Adverse event potential**
      - **Medication molecular make up (similar to something already on market or new formulation)**



# FDA's Risk Evaluation and Mitigation Strategies (REMS)

- REMS Elements:
  - Required
    - Assessment submission timetable
  - Optional
    - MedGuide
    - Communication Plan
    - Elements to Assure Safe Use (EASU)
    - Implementation System

# FDA's Risk Evaluation and Mitigation Strategies (REMS)

## • EASU Examples:

- Prescribers of the drug have specialized training/experience or certification
  - Dispensers of the drug are specially certified
  - Healthcare settings allowed to dispense limited
  - Patients utilizing the drug have safe use confirmation (lab tests, etc.)
  - Patient enrollment & specific monitoring
- Since March 25, 2008, 21 REMS Approved:
    - REMS for certain Opioids has been proposed and is currently being



# FDA's Action to Halt Marketing of Certain Unapproved Narcotic Drugs

- FDA sent warning letters March 30, 2009 to nine companies directing the companies to stop making and distributing 14 unapproved narcotic drugs marketed in several dosage forms
- Affected products included unapproved high concentrate oral solutions containing morphine sulfate and unapproved immediate release tablets containing morphine sulfate, hydromorphone, or oxycodone
- On April 9, 2009, FDA announced it was amending its previous action to allow continued marketing of a high concentrate morphine sulfate solution on an interim basis due to complaints from the pain mgmt. community.

# FDA Action to Halt Marketing of Certain Unapproved Narcotic Drugs

- This is not a recall and previously manufactured products may still be found on pharmacy shelves for a short period of time
- FDA states that "Consumers will continue to have access to FDA-approved narcotic drugs"
- FDA is working to ensure that all marketed unapproved drugs obtain approval or are removed from the market